Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UMB BANK, N.A., as Trustee,	)	
	)	
Plaintiff,	)	No. 1:15-cv-08725
	)	(GBD)(RWL)
vs.	)	
	)	
SANOFI,	)	
	)	
Defendant.	)	
----------	)	

VIDEOTAPED DEPOSITION OF S. ALBERT EDWARDS
New York, New York
Friday, March 8, 2019

Reported by:
KRISTIN KOCH, RPR, RMR, CRR
JOB NO. 156490

changing technologies, changes science, changing medicine; correct?

A. That's correct.

MR. MINTZ: Objection. Form.

Q. That's correct.

THE COURT REPORTER: I'm sorry?

MR. MINTZ: Objection to form.

Q. And you didn't actually have any firsthand experience with the Lemtrada application; correct?

A. And by firsthand experience you mean --

Q. You were not involved personally with respect to any aspect of the Lemtrada application to the FDA; correct?

A. No. No.

Q. After the FDA you spent a few years at a couple of other positions.

You were an assistant professor, correct, at Howard?

A. That's correct.

Q. You were a senior staff pharmacologist at the National Institute of Health?

"stated another way."

MR. MINTZ: Sorry. Which paragraph are we on?

MS. VENEZIA: End of 23, second to last sentence.

A. Okay. I see that. I'm with you.

Q. Isn't the converse also true?

A. In other words, let me clarify what I think you are saying, and that is even a product with negative clinical outcomes and otherwise negative attributes, is that where you are going?

Q. No.

A. Can fail to achieve approval?

Q. Let me see if I can help.

A. Okay.

Q. If you have a product where the regulatory strategy that's been employed is one that you would say is consistent with a diligent efforts obligation, but the product safety profile is such that the FDA is not willing to issue an approval, isn't that also the case, in other words, isn't it the case that you could have an impeccable regulatory

strategy, yet the FDA still deems the product not suitable for public use?

A. Yes, that can happen.

Q. If you go to pages -- I'm sorry -- paragraphs 28 to 29, there is a reference to the division of neurology products; correct?

A. Yes.

Q. And this division was actually formed after you left the FDA; correct?

A. Yes.

Q. Are you aware that a published report from 2014, which examined all of the existing FDA divisions, found that DNP was the slowest division at FDA in terms of product approval, were you aware of that?

A. I'm not aware of that, no.

Q. Would that have impacted your opinion in any way?

A. I wouldn't be surprised by that sort of outcome, because neurologic diseases are among the most difficult to research and find viable efficacy measures for.

Q. In paragraph 32, you talk about the FDA, and I am now sort of three-quarters of the

secrets, but I guess --

A. Well, let's say secrets from the point of view that one of those could surface and cause an RTF.

Q. And I guess what I was thinking is it seems possible to me that an -- FDA could think of an issue, notwithstanding all of its prior work in the six to seven, eight, nine years that you have talked about, that crystallizes in a way it had not crystallized before and, thus, raises additional or new concerns that it hadn't previously expressed. That's all I was trying to sort of get at.

A. Yes. And, you know, over a shorter period of time I have experienced that. We thought we had -- and you are just triggering a memory. We thought we had the ideal antibiotic answer to some of the most vexing infections that cancer patients get or that HIV patients get, suffering as sort of a side effect of their disease. We went through phase 1 planning, which was fairly complicated, because this drug had a five-day half-life. So it doesn't disappear from your body in a day. You

would have yielded a -- assuming correctly formatted data elements all in shape for review, this would have yielded an approval third or fourth quarter of 2013.

Q. So based on all of those assumptions that you just listed, that's how you reached your third or fourth quarter of 2013?

A. Right, that's my explanation.

Q. In footnote 56 you have a reference to the "timing assumes Sanofi used the correct people and resources to achieve these milestones."

What do you mean by "correct people and resources"?

A. Previously we discussed the TAP 85 gigabyte application and I listed some people and parameters that were present and, you know, I believe those resources are available either directly from Genzyme or they are available as contract resources from the contract research industry to fulfill those needs.

Q. And I believe you earlier said you did not know the number of people on the Lemtrada application. So are you saying here

approximately 60-plus days.

Q. And is it your view that Sanofi should have anticipated each component that the FDA requested at the pre-BLA meeting?

A. They certainly should have had access to pre-BLA meeting materials from at least Aubagio to be predictive of what FDA was going to ask them for. Moreover, just the primary tenet that FDA is always going to be concerned about safety, and so I would expect going into that meeting FDA is going to have a conversation with you about all the safety data surrounding Campath. That shouldn't be a surprise.

Q. And, in your view, is it typical for pharma companies to anticipate each request that the FDA might pose at a pre-BLA meeting?

MR. MINTZ: Objection to form.

A. It's typical for them to, let's say, do their best and try and anticipate every request that FDA has, yes.

Q. But you can't always anticipate every request; correct?

A. Right, you can't be perfect.

Q. Have you ever attended -- and I think I may have asked you this before, but apologies if I'm duplicating -- a pre-BLA meeting?

A. I have not attended a specific pre-BLA meeting, no.

Q. And you say "specific pre-BLA." I don't know if you are trying to make a distinction there.

A. Pre-NDA meeting, pre-IND meeting, those sorts of things.

Q. In your experience, is it uncommon for sponsors to receive follow-up from FDA at a pre-BLA meeting?

A. I guess I would say it's certainly not the norm to receive follow-up requests. One -- one would hope that going into that sort of a meeting you have an interaction with the agency, you find out all their needs, and then you kind of close things out when you leave -- leave the doorway.

Q. I know you said you hadn't attended a pre-BLA meeting, so what experience are you drawing that conclusion from?

A. The pre-IND meeting and NDA meetings that I attended.

Q. And so in the context of those meetings, you, yourself, have not experienced a situation in which the FDA requested follow-up items arising out of that meeting?

A. No. I am usually pretty relentless in terms of people doing -- do your homework, get it done early and get the data in front of the decision makers at FDA to get the yes.

Q. And is your experience typical of what other pharma companies with similarly-situated products see when they are at the pre-BLA meeting?

A. I -- I believe it is, especially when you have limited time to achieve a particular review date hanging over your head.

Q. And can you name any specific pharma companies that you are aware went through a pre-BLA meeting without receiving any follow-up from the FDA?

A. I'm not aware of any.

Q. Is it your view, based on the materials that you have reviewed, that Sanofi

regulatory intelligence and actively communicated with the FDA, it would have addressed the FDA's concerns well in advance of March 31, 2014, and FDA approval would have been achieved during December of 2013"; correct?

A. Yes.

Q. And there is no source cite for that; correct?

A. There is no source for that, that's correct. I think I earlier today traced you through my timing from the pre-BLA meeting in 2012 through a liberal sequence of activities to get to the third or fourth quarter of 20 -- 2013 for an approval.

Q. Right, we did speak about that, but you can't actually guarantee that approval would have occurred; correct?

MR. MINTZ: Objection to form.

A. I can't guarantee that approval would have occurred at that time. All I can do is reflect on the fact that approximately eleven months later, no new data, FDA did approve Lemtrada.

A. It would depend on the trial design and the specifics for that.

Q. Do you have an approximate ballpark?

A. I don't.

Q. Could those trials have been completed from start to finish in twelve months, including the recruitment of patients?

A. From start to finish, that would probably be difficult, but, you know, it would, I think, depend upon the level of recruitment that you could undertake once the -- once the study design was laid out.

Q. And, in your view, would it have been possible to prior to March 31 of 2014 have had recruited the patients, completed the trials, completed a submission to FDA and actually had FDA approve that submission?

MR. MINTZ: Objection to form.

It's -- objection to form.

A. Certainly for a promising drug like Lemtrada one would hope that that would all be doable within that time frame.

Q. Other than hoping that it would be doable, do you have any basis --

A. I don't have any -- I -- I have not delved into the specific step-by-step process to tease that out.

Q. And is it your opinion that putting aside whether the studies would have been completed by that time, that just initiating the study would have been sufficient for the FDA to get comfortable with approval?

A. I think it would have signaled -- sent a very strong signal to FDA to the neurology review division that Lemtrada had additional indications to offer and would change the regulatory landscape for the further review of it.

Q. Would that have guaranteed approval?

A. One would certainly hope so, but there is -- if you use the word "guarantee," I would have to say no.

Q. Can you point to any specific experience that you have had in which initiating such a study has led the FDA to reverse course or avoid a CRL, as you put it?

A. Not avoid a CRL, but I can tell you that TAP's consistent presence in the Lupron

the compounds that I work with had either backup compounds or additional indications that they wanted to pursue, and so the trending down of a single application would not end the drug's life at TAP, it would merely switch to another indication.

Q. But the drug life at Sanofi also did not end at the disability miss; correct?

A. Right.

Q. In 134, at the end of that you say: "Had Sanofi initiated a DVS study immediately after the CARE-MS-I results were reported, Sanofi would have avoided the CRL." And, again, what's your basis for that?

A. Again, it's the switching of development paths to something that is an unmet medical need which has a higher attention span at FDA and a higher possibility of succeeding.

Q. Sitting here today, you don't know whether the FDA would have approved Lemtrada without a CRL simply by virtue of a DVS study; correct?

MR. MINTZ: Objection to form.

A. I can't guarantee that approval, but

it would have given another avenue to approval.

Q. Similarly in 135 you talk about the revokal of the Lemtrada Fast Track designation.

Is it your opinion that initiating a DVS or PPMS study would have gotten Fast Track reinstated?

A. I think it would, yes.

Q. And does that opinion assume that at the time there was actually data to support reversal of disability?

A. I think there was at that time, yes.

Q. In 2012?

A. Yes.

Q. Is there any reason, in your view, why a pharmaceutical company would not want to initiate a study while an application was currently pending?

A. Would not want to initiate a study? There are probably reasons. I am not aware of any as I sit here right now why that wouldn't be the case.

Q. How about the risk of obtaining negative data from the ongoing study while you have a pending application with the FDA, is

only drug after drug, but they see patient experience after patient experience, and so for them to see someone or a sponsor who is willing to work on an unmet medical need like disability, for instance, knowing all the patients they have seen and all the trials that experience disability, just from a human point of view it's a very strong incentive for them to view your product in a positive way.

Q. The reviewers themselves don't actually have the final say; correct?

A. They don't have the final say, but they are the main basis for decision-making authority in the agency.

Q. I think you said that from a human point of view this would be a strong incentive, a very strong incentive for the reviewers to review -- to view your product in a positive way; correct?

A. Yes.

Q. But does that mean necessarily that the FDA would have had a different outcome?

MR. MINTZ: Objection to form. We have been down this road a while. Asked

and answered.

A. I -- I think I previously said I can't guarantee a positive outcome from this.

Q. In paragraphs 138 and 139 you cite a number of documents. These documents are all from the 2010 and early 2011 period.

Does that -- do you recall that? I know you don't have dates for all of these documents, but you do have some discussion in the text about some of the timing.

A. Right, yes.

Q. And so this would have been -- these documents would have been generated before the disability endpoint in the CAMMS 232 study was missed; correct?

A. Yes, that's correct. But bear in mind there is a difference between when, let's say, data and documents become final and turned over for sort of public consumption or announcement, and internal discussions in the company months or so back in terms of what the results are.

Q. But the fact that individuals were talking about the reversal of disability prior